

Exhibit 52

State of California ex rel. Ven-A-Care of the Florida Keys, Inc.
v. Abbott Laboratories, Inc., et al., Master Civil Action No. 01-12257-PBS,
Subcategory Case No. 06-11337

Exhibit to the December 21, 2009 Declaration of Philip D. Robben in Support
of Defendants' Motions for Partial Summary Judgment



DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of Inspector General

Memorandum

Date NOV 6 1992

From

Bryan B. Mitchell *Bryan Mitchell*
Principal Deputy Inspector General

Subject

Physicians' Costs for Chemotherapy Drugs (A-02-91-01049)

To

William Toby, Jr.
Acting Administrator
Health Care Financing Administration

The attached final management advisory report summarizes the results of our review of physicians' costs for chemotherapy drugs. The review was undertaken at the request of the Health Care Financing Administration (HCFA). The objective of this review was to provide HCFA with information on physician costs for 13 high dollar volume chemotherapy drugs paid for under the Medicare program. Our review was limited to a small judgmental sample of physicians in New York State.

Our results indicate that, for the physicians surveyed, the 13 chemotherapy drugs can be purchased at amounts below the established average wholesale price (AWP) and that AWP is not a reliable indicator of the cost of a drug to physicians. Physicians can usually maximize cost savings by ordering some drugs directly from the major manufacturers who establish a single price for the entire country.

In addition to addressing drug costs, we evaluated costs associated with wasted and spoiled drugs, spilled drugs, storing the drugs, and bad debts. For the physicians surveyed, we found that these costs are minimal and should not have great impact on providing the drug.

We believe that, in gathering invoice prices as part of the carrier surveys required by regulation, HCFA should consider the source physicians use to obtain drugs. The survey results should be adjusted to the lowest price available in the marketplace when physicians indicate purchases at higher prices from pharmacies and wholesalers for drugs that could have been bought directly from manufacturers at lower prices.

We are recommending that HCFA define reimbursement policy to encourage physicians to purchase drugs using the most economical means available. The HCFA should also establish uniform survey criteria to be used by the carriers to determine estimated acquisition cost and set uniform policy for carriers' evaluation of drug

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inventory, waste, and spoilage costs. In addition, HCFA should revise its coding and reimbursement systems to pay for drugs based on the dosage actually administered.

In responding to the draft report, HCFA concurred with the recommendations to establish uniform survey criteria and uniform policy for evaluation of drug costs. The HCFA, however, believed that it would require additional information to evaluate its position on the remaining recommendations. The Office of Inspector General agrees that further study of the costs and payments for chemotherapy drugs is warranted; accordingly, we intend to expand our survey through a nationwide review during Fiscal Year 1993.

Please advise us, within 60 days, on actions taken or planned on our recommendations. If you have any questions, please call me or have your staff contact George M. Reeb, Assistant Inspector General for Health Care Financing Audits at (410) 966-7104. Copies of this report are being sent to other interested Department officials.

Attachment

Department of Health and Human Services
**OFFICE OF
INSPECTOR GENERAL**

**PHYSICIANS' COSTS FOR
CHEMOTHERAPY DRUGS**



NOVEMBER 1992 A-02-91-01049



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Principal Deputy Inspector General

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Physicians' Costs for Chemotherapy Drugs (A-02-91-01049)

To

William Toby, Jr.
Acting Administrator
Health Care Financing Administration

A handwritten signature in black ink that reads "Bryan Mitchell".

This final management advisory report summarizes the results of our review of physicians' costs associated with chemotherapy drugs for Medicare patients. The review was undertaken at the request of the Health Care Financing Administration (HCFA), in connection with changes to Medicare reimbursement for physician services mandated by section 6102 of the Omnibus Budget Reconciliation Act of 1989 [Public Law 101-239] which added section 1848 to the Social Security Act. In November 1991, HCFA published its final rule (effective January 1, 1992) basing payment for drugs on the lower of the estimated acquisition cost or the national average wholesale price (AWP). The estimated acquisition cost is determined based on carrier surveys to determine the actual invoice prices. The carrier may also consider factors such as inventory, waste, and spoilage in calculating the estimated acquisition cost.

The objective of this review was to provide HCFA with information on physician costs for 13 high dollar volume chemotherapy drugs paid for under the Medicare program.¹ Specifically, our review addressed concerns relating to physicians' costs to purchase the drugs and other associated costs that might be considered along with the price of chemotherapy drugs. The review examined physicians' costs for the drugs in relation to the AWP published in sources such as the Drug Topics Red Book (Red Book).

Our review was limited to a small judgmental sample of patients and physicians in New York State. We also held discussions with representatives of HCFA, the American Society of Clinical Oncology (ASCO) and the Medicare carriers for the States of New York and Tennessee. In addition, we contacted manufacturers of chemotherapy drugs and the publisher of the Red Book.

¹ For the purposes of this review, high dollar volume chemotherapy drugs were defined as those drug codes for which Medicare Part B allowed at least \$1 million for each drug during 1989. In addition, at the suggestion of the American Society of Clinical Oncology, we included the drug Carboplatin in the review.

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Our results indicate that, for the physicians surveyed, the 13 chemotherapy drugs can be purchased at amounts below AWP and that AWP is not a reliable indicator of the cost of a drug to physicians. Physicians can usually maximize cost savings by ordering some drugs directly from the major manufacturers who establish a single price for the entire country.

In addition to addressing drug costs, we evaluated costs associated with wasted and spoiled drugs, spilled drugs, storing and ordering the drugs, and bad debts. For the physicians surveyed, we found that:

- o under the present Medicare coding system, physician claims do not always reflect the dosage actually administered;
- o Medicare payments partially compensate for the costs of wasted drugs;
- o in certain instances, credits to physicians for spoiled drugs are allowed by manufacturers and wholesalers;
- o spillage is a relatively rare occurrence and has little impact on physician costs;
- o the incremental costs incurred by physicians for storing the drugs are insignificant and should not impact the cost of providing the drug; and
- o bad debts attributed to Medicare beneficiaries are less than 1 percent of the amounts owed to the physicians.

We also believe that, in gathering invoice prices as part of the carrier surveys required by regulation, HCFA should consider the sources used by physicians to obtain drugs. The survey results should be adjusted to the lowest price available in the marketplace when physicians indicate purchases at higher prices from pharmacies and wholesalers for drugs that they could have bought directly from manufacturers at lower prices. Therefore, we are recommending that HCFA:

- o define reimbursement policy to encourage physicians to purchase drugs utilizing the most economical means available in the marketplace;
- o establish uniform survey criteria to be used in determining the drug payment levels;
- o set uniform policy for carriers' evaluation of drug inventory, waste, and spoilage costs; and

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- o revise its coding and reimbursement systems to pay for drugs based on the dosage actually administered.

In responding to the draft report, HCFA concurred with the recommendations to establish uniform survey criteria and uniform policy for evaluation of drug costs. The HCFA, however, believed that it would require additional information to evaluate its position on the remaining recommendations. The Office of Inspector General (OIG) agrees that further study of the costs and payments for chemotherapy drugs is warranted; accordingly, we intend to expand our survey through a nationwide review during Fiscal Year (FY) 1993. The HCFA comments are presented as Appendix V to this report.

BACKGROUND

The Social Security Act, sections 1861 and 1862, provide coverage for medically necessary physician services as well as drugs, including chemotherapy agents, which are furnished "incident to" physician services. Payment is provided under the Supplementary Medical Insurance program (Medicare Part B). For beneficiaries receiving chemotherapy services in a physician's office, the Medicare program will pay for an office visit and the administration of the drug, as well as the drug itself.

The HCFA has primary administrative responsibility for the Medicare program. As such, HCFA contracts with carriers to make payments for medical and other health services covered under Medicare Part B. At the time of our review, the Medicare contractors we contacted generally based the payment for drugs on estimated costs obtained from wholesale guides such as the Red Book. The Red Book refers to such estimated costs as the "average wholesale price." Equicor, the Medicare carrier in Tennessee, based its payment for five chemotherapy drugs on physician invoice prices.

In June 1991, HCFA published a proposal to change the methodology for reimbursing drugs under Medicare Part B. In connection with developing the proposed rules, HCFA requested that the OIG study the utilization for certain drugs furnished by oncologists and the amounts they pay for drugs. Our review covered 13 chemotherapy drugs, 12 drugs requested by HCFA, and the drug Carboplatin as suggested by ASCO. Medicare allowances for the 18 billing codes (13 drugs) representing high dollar volume chemotherapy drugs for 1989 totaled \$67.8 million nationwide.

In addition to the cost of the drugs, HCFA and ASCO suggested that we consider related costs associated with wasted and spoiled drugs, spilled drugs, storing and ordering the drugs, and the bad debts associated with the beneficiary's payment

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amounts. Other areas suggested for review included the variance of drug costs based on the size of the physician's practice, the location of the practice, and the source of supply.

In November 1991, HCFA published its final rule (effective January 1, 1992) basing payment for chemotherapy drugs as follows:

- o Single-Source Drugs - the lower of the estimated acquisition cost or the national AWP. The estimated acquisition cost is determined based on surveys of the actual invoice prices paid for the drug. The carrier may also consider factors such as inventory, waste, and spoilage in calculating the estimated acquisition cost.
- o Multiple-Source Drugs - the lower of the estimated acquisition cost or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug.

METHODOLOGY

The objective of our review was to provide HCFA with information on physician costs for 13 high dollar volume chemotherapy drugs. Specifically, our review addressed concerns relating to physicians' costs to purchase the drugs and other associated costs that might be considered along with the price of chemotherapy drugs. In order to satisfy the objective, we judgmentally selected five New York State (NYS) physicians (or physician groups) whose Medicare billing records for 1991 included at least several of the high dollar volume chemotherapy drugs. The physicians selected are serviced by one of two Medicare carriers: Empire Blue Cross Blue Shield (Empire) which serves as the carrier for 16 counties in and surrounding New York City, and Blue Shield of Western New York (BSWNY) which serves as the carrier for upstate New York.

For the physician group serviced by BSWNY, the review included payments for drugs between January and July 1991. For the Empire service area, we reviewed drug payments made from April to June 1991. Further information about the physicians included in the review is presented in Appendix I.

We also obtained information from the medical director of Equicor about their limited survey of invoice costs for chemotherapy drugs and held discussions with the third New York carrier, Group Health Incorporated.

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In addition, we contacted manufacturers with Red Book listings for the high dollar volume chemotherapy drugs. For 1990 and 1991, the Red Book included listings for 21 manufacturers offering 56 such products. Our contacts included meetings, correspondence or discussions with 4 of these manufacturers offering 23 of the products. We also reviewed catalogues and price lists from oncology wholesalers and consulted with officials representing the Red Book.

Field work was conducted during FY 1991 at Empire, the physicians' offices, and a manufacturer's headquarters.

RESULTS OF REVIEW

Our results indicate that, for the physicians surveyed, the 13 chemotherapy drugs can be purchased at amounts below AWP and that AWP is not a reliable indicator of the cost of a drug to physicians. We also found that the costs associated with wasted and spoiled drugs, spilled drugs, storing the drugs, and bad debts have little impact on physician costs. In addition, under the Medicare coding system, physician claims do not always reflect the dosage actually administered.

DRUG COSTS

To determine the relationship between AWP and the actual cost of chemotherapy drugs to oncologists, we compared physician invoices for the high dollar volume drugs to the AWP for like units of the same drug. In order to understand the cost/AWP relationship, we held discussions with officials representing the Red Book and drug manufacturers.

Our review of invoices revealed that the 13 chemotherapy drugs can be purchased at amounts below AWP. This fact indicated that AWP is not a reliable indicator of physician cost; indeed, Red Book officials confirmed that the AWP is not designed to reflect physicians' costs (see Appendix II). We also found that the relationship between AWP and cost for multiple-source drugs varies, depending in large part on the manufacturer.

In addition, misconceptions among physicians about AWP and cost contributed to complaints about Medicare reimbursement for chemotherapy drugs. For example:

- o a physician stated he thought that only large institutions can obtain drugs at prices as low as AWP;

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- o several physicians advised us that discounts offered to small practitioners for drugs usually pertain only to goods with a limited shelf life (short dated); and
- o a carrier, based on input from physicians, represented that discounts below AWP usually apply only to multiple-source drugs.

Our analysis disproved these misconceptions and established that high dollar volume chemotherapy drugs are available at a cost below AWP. For example, one of the five providers (provider #3) submitted a claim for drugs administered on March 7, 1991. Analysis showed that each drug's cost was below the AWP and that the total cost for the drugs claimed was 48 percent of AWP.

<u>Drug</u>	<u>Dose</u>	<u>AWP</u>	<u>Physician Cost</u>
DOXORUBICIN	70 MG	\$438.10	\$180.00
CYCLOPHOSPHAMIDE	500 MG	24.73	19.28
VINCRISTINE	2 MG	<u>63.52</u>	<u>54.50</u>
TOTAL		<u>\$526.35</u>	<u>\$253.78</u>

Summary results of our review of physician invoices for chemotherapy drugs are presented in Appendix III.

We also found that the physicians can usually maximize cost savings by ordering the drugs directly from the manufacturers. Major manufacturers informed us that they establish a single price for physicians throughout the entire country, regardless of quantities ordered. Our comparison of manufacturers' invoices from Equicor to those from NYS physicians supports the single price list representation.

In addition to the cost savings available to physicians from manufacturers, minimum order requirements (e.g., \$100 per order) for manufacturers may be lower than for oncology wholesalers. While several major manufacturers sell directly to physicians, not all manufacturers will do so. Consequently, the surveyed physicians also obtained oncology drugs from wholesalers and pharmacists. The surveyed physicians dealt with oncology wholesalers because they received more favorable credit terms and could easily place a single order, as well as maintain a source of supply for drugs

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which cannot be purchased directly. Finally, surveyed physicians who prefer the convenience of obtaining the drugs from retailers (pharmacies) admitted that such arrangements can be costly.

The second physician assertion is that discounts offered to small practitioners for drugs usually pertain only to goods with a limited shelf life (short dated). We tested the assertion by reviewing the prices of a wholesaler who lists expiration dates in the catalogue. Our analysis of the cost/AWP correlation based on expiration dates showed that physician cost was linked more to manufacturer sources than to expiration dates.

Physicians had also asserted that discounts below AWP generally apply only to multiple-source drugs. Our review of physician invoices, however, showed that the correlation between AWP and cost remains fairly consistent for both single-source and multiple-source drugs from a given manufacturer.² For example, comparison of the actual cost to the AWP for Cyclophosphamide, 500 mg, showed that one brand name manufacturer sells this drug at 20 percent below AWP while another sells it at 59 percent below AWP. Although neither the manufacturers nor the Red Book could explain these relationships, we found that products of the first manufacturer were generally available at 20 percent below AWP while products of the second manufacturer were generally available at 55 to 60 percent below AWP. We, therefore, conclude that the cost/AWP relationship depends on the manufacturer regardless of whether the drug is available from multiple sources (see Appendix III). For example, oncology wholesalers tended to discount all single- and multiple-source drugs from one major manufacturer at a uniform percentage below the AWP.

While a greater awareness of these relationships by physicians could lead to more advantageous purchasing decisions, we detected other lost opportunities to minimize drug costs. For example, during our site visits, we noted instances among three of the surveyed physicians when 1 to 2 percent cash discounts, available for payment within 30 days, were not claimed.

² In this regard, it should be noted that major manufacturers informed us that Red Book, and not the manufacturers, determines the AWP. However, Red Book officials advised us that manufacturer input is their primary source of pricing information.

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**Wasted and
Spoiled
Drugs**

To address concerns that costs for wasted and spoiled drugs increase physician costs by up to 30 percent, we solicited comments from both physicians and manufacturers. We also compared dosages claimed on Medicare records to dosages administered (per medical records) for analytical purposes.

The results indicate that drug manufacturers and Medicare bear a portion of the costs for wasted and spoiled drugs. Physicians defined waste to include the unused drug left in a vial, as well as expired goods. Surveyed physicians reported that they either could not reduce such cost by returning oversupplies or expired goods, or that the paperwork involved was too burdensome. However, one of the physicians interviewed estimated that he can succeed in getting credit for returned goods up to 50 percent of the time.

Our review of return policies in manufacturer and wholesaler catalogues and inquiry of manufacturer officials confirmed that credits to physicians are allowed in certain instances. For example, while suppliers may not accept returns of certain drugs under any conditions, a major manufacturer informed us that they will go out of their way to accommodate such requests. One major manufacturer will even provide shipping materials and assist the physician in packing the goods for return. Furthermore, virtually all of the paperwork involved would be handled by the sales representative rather than the physician.

Since most of the physician practices we visited were not large, the major complaints about waste centered around the inability to use the entire vial before the contents go bad. We were also informed that product stability is impaired once a vial has been invaded and that powdered drugs have short shelf lives once mixed.

Our analysis indicates, however, that under the present coding system, Medicare may reimburse the physician for the "wasted" drug. A comparison of dosages claimed to dosages actually administered and discussions with all three New York carriers indicated that this is a by-product of the Medicare coding and reimbursement system for drugs. For example, HCFA includes only one code for Fluorouracil, in the 500 mg dose. If the physician administers 750 mg, he/she must, therefore, bill Medicare for 1,000 mg (i.e., two times the 500 mg dose). The New York carriers indicated that they generally pay for the higher dosage claimed because it is not cost beneficial to establish a mechanism to do otherwise.

Appendix IV provides the results of our analysis of Medicare reimbursement for wasted drugs at four of the five physicians. Medical records at the remaining physician indicated that no wasted drug had been billed.

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Spillage

Because of concerns about the costs associated with accidental breakage and loss of a drug, we inquired about spillage during our site visits at four of the physicians.

The sampled physicians felt that spillage was a minor issue; in some cases, they could not even recall when they had last experienced such a loss. Therefore, based on our limited review, we believe that spillage does not affect drug costs to any appreciable extent.

Storage

Through inquiry and observation, we evaluated assertions to the effect that administrative costs for maintaining inventory can be sizable.

During site visits, sampled physicians informed us that they maintain only a small drug inventory in order to reduce waste and improve cash flow. If unanticipated needs occasionally leave these physicians short, they may have to rely on higher-priced local sources of supply although one of the larger practices borrows drugs from hospitals until their own order is received.

To gather further information on this subject, we toured four of the practices. We learned that the drugs requiring refrigeration can be safely stored in normal household refrigerators. In two instances, sandwiches and other personal items were stored in the same refrigerator as the oncology drugs. In another instance, only drugs and related items were stored in a refrigerator that was less than half full.

Drugs not requiring refrigeration were stored either in cabinets or on open shelves. In several cases, there was empty space available in these cabinets. For three of the four practices toured, the drugs were stored in rooms used for other purposes, such as patient treatment rooms. Under these circumstances and given that the goal is to minimize inventory, we believe that storage costs, per se, are not a major cost factor. Therefore, we cannot confirm the assertion that storage costs significantly affect the cost of chemotherapy drugs.

Ordering

Since concerns were raised about the sizable costs of procuring the drugs, we analyzed such cost factors through inquiry and observation.

We found that two of the five practices did not include a chemotherapy nurse; consequently, the doctors ordered their own drugs. In the other practices, this duty

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was carried out by the chemotherapy nurse. In each case, examination of drug invoices indicated that several sources of supply were used. The physicians and nurses informed us that some manufacturers visit their offices regularly, and that some suppliers send out price lists and catalogues. In other cases, the physician must call several suppliers to determine the best prices available.

We did not estimate the time involved or the costs associated with ordering drugs; therefore, we cannot draw any conclusions on drug ordering costs.

Bad Debts

To analyze industry assertions that bad debts arising from unpaid 20 percent coinsurance is a hidden cost of administering drugs, we discussed bad debts with each of the physicians. Although two of the surveyed physicians were satisfied with their collections, two cited factors particular to an oncology practice as contributing to unusually high bad debt expenses. For example, patients may well have exhausted their assets in paying for tests, surgeries and hospital stays before chemotherapy even begins. Although the larger practices would pursue recoveries from estates or collection agencies if the patient expired, the smaller practices tended to just write-off amounts not collected from Medicare or other third party insurers.

We also tested bad debt expenses by analyzing all drug claims for 8 to 10 patients for each physician. The review was designed to include drug claims paid from January to July 1991 at BSWNY and drug claims paid from April to June 1991 at Empire. We noted that, in many instances, physicians filed separate claims for drugs and nondrug services; nonparticipating physicians sometimes did this to accept assignment on only one of the claims.³ Results for the physicians reviewed were:

<u>Provider</u>	<u>Bad Debt as Percent of Amount Due</u>
I	0.00%
II	Not Available
III	0.03%
IV	0.00%
V	0.86%

³ In some cases, the physician would accept assignment for the nondrug services only to maximize revenues for the drugs; in other instances, the decision was based on the patient's ability to pay.

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While these statistics appear to indicate that bad debts are almost nonexistent (less than 1 percent), misconceptions among the physicians interviewed may have led to an overstatement of losses attributable to bad debts. For example, representatives of participating physicians referred to the uncollectible difference between amounts claimed and amounts allowed as "bad debts," even though the participation agreement prohibits collection of such amounts.

While the physicians were not billing these amounts to patients or secondary insurers, their records of account carry the receivables at the gross amount billed to Medicare. Upon payment from Medicare and other liable parties, the difference between the billed amount and Medicare's allowance is routinely written-off the books.

CONCLUSIONS

This review represents a limited analysis of physicians' costs for 13 chemotherapy drugs. The conclusions reached may not apply in all cases. It is recommended that HCFA substantiate these conclusions either through a sample of physicians and patients nationwide or by other means to assure widespread applicability.

For the physicians surveyed, however, we found that:

- o the 13 high dollar volume chemotherapy drugs can be purchased at amounts below AWP;
- o AWP is not a reliable indicator of the cost of a drug to physicians;
- o usually, the most economical method for ordering drugs is directly from the manufacturer;
- o under the present Medicare coding system, physician claims do not always reflect the dosage actually administered;
- o Medicare payments partially compensate for the costs of wasted drugs;
- o in certain instances, credits to physicians for spoiled drugs are allowed by manufacturers and wholesalers;

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- o spillage is a relatively rare occurrence and has little impact on physician costs;
- o the incremental costs incurred by physicians for storing the drugs are insignificant and should not impact the cost of providing the drug; and
- o bad debts attributed to Medicare beneficiaries are less than 1 percent of the amounts owed to the physicians.

RECOMMENDATIONS

In addition to these factors, HCFA should consider the source used by physicians to obtain drugs when gathering the invoice prices through carrier surveys required by regulation. The survey results should be adjusted to the lowest price available in the marketplace when physicians indicate purchases at higher prices from pharmacies and wholesalers for drugs that they could have bought directly from manufacturers at lower prices. Therefore, we are recommending that HCFA:

- o define reimbursement policy to encourage physicians to purchase drugs utilizing the most economical means available in the marketplace;
- o establish uniform survey criteria to be used in determining the drug payment levels;
- o set uniform policy for carriers' evaluation of drug inventory, waste, and spoilage costs; and
- o revise its coding and reimbursement systems to pay for drugs based on the dosage actually administered.

HCFA Comments

The HCFA did not agree with the first recommendation encouraging physicians to utilize the most economical means available to purchase drugs, stating that they lack assurance that a substantial number of physicians can obtain drugs at the lowest

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price available. The HCFA, therefore, proposes to perform surveys of physicians to determine the estimated acquisition cost to physicians for chemotherapy drugs.

OIG Response

The HCFA's comments refer to the possibility that a substantial number of physicians may not have access to the lowest price available in the marketplace. The OIG neither meant to imply, nor can we substantiate, that the lowest cost version of any drug is widely available. The preliminary survey results do, however, indicate that major manufacturers make many chemotherapy drugs widely available at a uniform nationwide price which may be lower than the price for the same item purchased elsewhere. Accordingly, we recommend that HCFA consider the most economical source of supply (for example, the drug manufacturer rather than an oncology wholesaler) in defining estimated acquisition costs. We remain concerned that unless this issue is addressed in policy development, the results of surveys on estimated acquisition costs may not reflect the most economical decisions available to the physician.

HCFA Comments

The HCFA concurred with the second and third recommendations and suggested a few technical changes to the final report.

OIG Response

We have incorporated HCFA's technical comments into this final report where applicable. In addition, we would be happy to discuss these matters further in planning the expanded review.

HCFA Comments

The HCFA disagreed with the fourth recommendation to revise the coding and reimbursement system to better reflect actual dosages administered. In its response, HCFA stated that our preliminary work was too limited to warrant such actions, but encouraged us to gather further information on the costs and payments for wasted drugs. The HCFA also noted that it is considering alternative coding systems which may result in more accurate reporting of dosages administered.

OIG Response

The OIG agrees that further study of the costs and payments for chemotherapy drugs is warranted; accordingly, we intend to expand our survey through a nationwide review during FY 1993.

APPENDICES

APPENDIX I

PROVIDER PROFILE

Provider #1 is a participating physician within the service area of BSWNY. This provider is an ASCO member with a primary specialty of medical oncology. The four physicians in the group perform services in several upstate locations. The provider estimates that Medicare accounts for 65 percent of their patient load. Allowed charges for chemotherapy drugs for the first half of 1991 amounted to approximately \$50,000.

Provider #2 is a sole practitioner in New York City. For the first half of 1991, Medicare allowances for drugs at this practice were approximately \$35,000. This physician participates in the Medicare program and estimates that 20 to 30 percent of the chemotherapy patients are covered by Medicare.

Provider #3 is a member of a group practice in New York City. This participating physician estimates that 45 percent of total patient load (and 45 percent of chemotherapy patients) are entitled to Medicare benefits. Medicare allowances for drugs administered by this member of the group were \$28,000 (19 percent of total Medicare allowances) during the first half of 1991.

Provider #4 is a sole practitioner in the suburbs of New York City. The provider specializes in medical oncology and hematology and is a member of ASCO. This nonparticipating physician estimates that 40 percent of his patients (30 to 35 percent of chemotherapy patients) are Medicare beneficiaries. Allowed charges for drugs for January through June 1991 totalled \$49,000, representing 38 percent of total allowances.

Provider #5 is a member of a large group practice in suburban New York. This provider, an ASCO member, specializes in medical oncology. Though a nonparticipant at the time of our visit, the physician intended to become a participating physician, effective January 1992. Medicare allowances for drugs during the first half of 1991 represented 18 percent (\$19,000) of the member's total Medicare allowances. This physician estimates that 50 percent of his patients and 75 percent of the chemotherapy patients served in the office are covered by Medicare.

APPENDIX II

RED BOOK

The Medicare Carriers Manual, Part 3, currently advises carriers to obtain the approximate cost for drugs from sources such as the Red Book, Blue Book or Medispan. Medicare Part B has considered the AWP listed in such publications as an indication of drug cost. Since the Red Book is the source used by both Empire and BSWNY, we contacted Red Book officials.

The purpose of our discussions with representatives of the Red Book was to obtain background information on the usefulness of the national AWP as a measure of the estimated acquisition cost for drugs to physicians. The Red Book officials explained that the primary source of information for the published AWP is the drug manufacturers. They corroborate this with information from wholesalers and claims processors. Since these sources may provide different AWPs for the exact same drug, the Red Book uses algorithms to weight the information based on general information about distribution channels and relative sales volumes for the various sources.

However, Red Book officials advised us that their data on AWPs, like the information used by the Blue Book or Medispan, is meant to approximate the cost to retailers (pharmacists) only. These officials also emphasized that their focus has always been the pharmacy sector which is their chief market and that this is clearly understood by those who supply information to the Red Book.

We note, too, that the table of contents and cover sheet to the 1991 Red Book clearly state in bold face print that this is the "Annual Pharmacists' Reference." The foreword to the Red Book reinforces this information and states that, "The pricing section is the most complete and reliable source of its kind available to a pharmacy today."

Since the Red Book does not represent its AWP as a measure of the physician's acquisition cost for drugs, we compared physicians' invoice costs to Red Book's AWP. We found that such costs were not only generally significantly less than AWP, but that there can be a wide variety of AWPs for a given drug depending on the manufacturers and the form of the drug (e.g., solution, powder, lyophilized powder). For example, the highest Red Book AWP among 8 manufacturers of Methotrexate Sodium, 50 mg (\$15.43) was over two and a half times as much as the lowest published AWP (\$5.75). Considering that we also found that there is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of the physician's acquisition cost, we do not feel that AWP provides a useful measure of the acquisition cost for a drug to physicians.

APPENDIX III

INVOICE COSTS

Expressed as a Percentage below the AWP

DRUG	BRAND NAME MFRS	GENERIC MFRS	ONCOLOGY WHOLESALERS	SINGLE SOURCE
BLEOMYCIN	20%	A	12 TO 17%	YES
CARBOPLATIN	20%	A	17%	YES
CISPLATIN	B	A	17%	YES
CYCLOPHOSPHAMIDE	20 TO 59%	B	17 TO 22%	NO
DOXORUBICIN	56 TO 59%	61%	59 TO 60%	NO
ETOPOSIDE	20%	A	17 TO 18%	YES
FLUOROURACIL	B	B	45 TO 68%	NO
INTERFERON	B	B	9 TO 14%	NO
METHOTREXATE SODIUM	B	60% TO 79%	68 TO 83%	NO
MITOMYCIN	20%	A	17%	YES
THIOTEPA	B	A	16%	YES
VINBLASTINE SULFATE	63%	B	50 TO 64%	NO
VINCRISTINE SULFATE	83%	B	81 TO 82%	NO

A - Single Source Drug - no generic manufacturer

B - No observation of direct purchase from drug manufacturer

APPENDIX IV

MEDICARE PAYMENTS FOR WASTED DRUG
 Expressed as a Percentage of Drug Dosage Claimed

DRUG	PROVIDER I	PROVIDER III	PROVIDER IV	PROVIDER V
BLEOMYCIN	0%	0%	---	33%
CARBOPLATIN	3%	0%	0%	0%
CISPLATIN	---	---	40%	30%
CYCLOPHOSPHAMIDE	4%	2%	20%	8%
DOXORUBICIN	1%	3%	36%	13%
ETOPOSIDE	21%	---	40%	33%
FLUOROURACIL	20%	22%	34%	33%
INTERFERON	---	17%	---	0%
METHOTREXATE SODIUM	1%	11%	44%	35%
MITOMYCIN	3%	---	40%	20%
THIOTEPA	48%	---	0%	---
VINBLASTINE SULFATE	50%	53%	39%	50%
VINCRISTINE SULFATE	12%	0%	0%	4%

We calculated the percentage of wasted drug which was included in Medicare's payment for the drug thusly:

1. For each patient sampled, we examined the medical record for every billing for a high dollar volume chemotherapy drug during the period under review.
2. For each billing, we compared the dosage claimed to the actual dosage administered. The difference between the two is considered as waste reimbursed by Medicare.
3. For each provider, we grouped the results according to the drug administered
4. For each drug, we eliminated obvious errors (such as instances when an adjustment claim for additional reimbursement was pending). To calculate the weighted average waste for the drug, we divided the total reimbursed waste for that drug among sampled billings by the total dosages claimed.

NOTE: Medical records at Provider II indicated that no wasted drugs had been billed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Care
Financing Administration

Date

JUL 20 1992

From

William J. Toby, Jr.

William Toby, Jr.

Acting Administrator

Subject

Office of Inspector General (OIG) Draft Management Advisory Report:
"Physicians' Costs for Chemotherapy Drugs," A-02-91-01049

To

Inspector General
Office of the Secretary

Memorandum

We have reviewed the subject draft management advisory report which summarizes the results of OIG's review of the Health Care Financing Administration's (HCFA) proposal to change the methodology used to reimburse for chemotherapy drug usage. The review was undertaken at our request. The objective of the review was to provide HCFA with information on physician costs for 13 high volume dollar chemotherapy drugs paid for under the Medicare program.

OIG found that the physicians surveyed in the study could purchase the 13 chemotherapy drugs at amounts below the established average wholesale price (AWP) which is used to set the Medicare reimbursement rate. Therefore, the AWP was not found to be a reliable indicator of the cost of those drugs to physicians. OIG also evaluated the costs associated with wasted and spoiled drugs, spilled drugs, storing and ordering drugs, and bad debts. OIG found that these associated costs should not significantly increase the amounts Medicare reimburses physicians for the 13 chemotherapy drugs reviewed.

OIG recommends that HCFA:

- o define reimbursement policy to encourage physicians to purchase drugs utilizing the most economical means available in the marketplace;
- o establish uniform survey criteria to be used in determining the drug payment levels;
- o set uniform policy for carriers' evaluation of drug inventory, waste and spoilage costs; and

revise its coding and reimbursement systems to pay for drugs based on the dosage actually administered.

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HCFA concurs with the second and third recommendations, and we nonconcur with the first and last. We believe that additional study which would include data on providers in rural areas is needed before we can justify using the results of this study to set a national payment policy for chemotherapy drugs. Therefore, we are requesting that OIG provide HCFA with additional information. Our specific comments are attached for your consideration.

We thank you for your efforts and hope that you will continue to assist HCFA in obtaining the necessary data needed to substantiate policy changes. We also appreciate the opportunity to review and comment on this draft report. Please advise us if you agree with our position on the report's recommendations at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on Office of Inspector General (OIG) Draft Management
Advisory Report - "Physicians' Costs for
Chemotherapy Drugs," A-02-91-01049

Recommendation 1

HCFA should define reimbursement policy to encourage physicians to purchase drugs utilizing the most economical means available in the marketplace.

HCFA Response

HCFA does not concur with the recommendation. We are not prepared to agree that HCFA should reimburse physicians at the lowest price available in the marketplace without further evidence that a substantial number of physicians have access to that price.

In our final rule on physician payment reform, we discussed the general drug payment policy. We will pay for drugs at the lesser of the average wholesale price (AWP) or estimated acquisition cost (EAC). To make an estimate of acquisition costs for high volume and high cost drugs, we plan to have selected Medicare carriers survey physicians' costs for these drugs. Unless we have evidence to the contrary, we plan to use a statistical measure of our survey results, such as the average or median to determine the EAC. The surveys will also provide us with a means to validate the conclusions made by OIG in this study.

Recommendation 2

HCFA should establish uniform survey criteria to be used in determining the drug payment levels.

HCFA Response

HCFA concurs with the recommendation. However, we would appreciate any assistance OIG can provide, based on its study, to aid us in establishing a set of survey criteria for use by Medicare carriers.

Recommendation 3

HCFA should set uniform policy for carriers' evaluation of drug inventory, waste and spoilage costs.

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HCFA Response

HCFA concurs with the intent of the recommendation. Although the scope of the review was limited, we were interested to see that these types of administrative expenses were not found to be extensive. We have received many comments from oncologists and the oncology specialty groups asserting that these costs range from 25 percent to 40 percent of the AWP of the drug. However, these assertions have never been supported by any documentation. We would appreciate any assistance OIG can offer in the methods used in evaluating drug inventory, waste and spoilage.

Recommendation 4

HCFA should revise its coding and reimbursement systems to pay for drugs based on the dosage actually administered.

HCFA Response

HCFA does not concur with the recommendation. Because the review was limited, we believe OIG's findings are inconclusive. Again, we would encourage OIG to expand the study. It was of interest to note that the New York Medicare carriers stated they believed it was not cost beneficial to establish a mechanism to adjust for the dosage actually used. This position should be pursued and studied by OIG if they have not already done so.

If we paid for the actual dosage used and physicians claimed some allowance for waste for the remainder, we may not be any better off than paying for the dosage ordered. It was not clear from the report whether drug companies were accommodating physicians for returned goods that were unused (left in the vial) or expired goods. Also, in situations where the product stability is impaired once a vial has been invaded, we question whether or not it would be reasonable to expect the physician to absorb the cost of any wastage.

HCFA is currently evaluating the possible use of the New Drug Application number or the National Drug Code number on the claim form to help alleviate the dosage size problems. It has not yet been determined if the use of either of these numbers would achieve the desired result of more accurate reporting dosage amounts.

Technical Comments

Auditor's Note: At this point, HCFA raised several questions which we will address in planning the expanded nationwide review.